Dated: July 13, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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BILLING CODE 4160–01–F

[Docket Nos. 95P–0061, 95S–0117, 95S–0126, and 95S–0135]

Patent Term Expiration Dates for Patents Extended by the Uruguay Round Agreements Act; Submission by Applicants of New Drug and New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its position on patent information submitted by applicants of new drug applications (NDA's) and new animal drug applications (NADA's). Patent term expiration dates for certain patents that are subject to both the Uruguay Round Agreements Act (URAA) and the patent term extension provisions of the United States Code should be calculated in accordance with the Patent and Trademark Office's (PTO's) determination of June 7, 1995. FDA will not publish dates that the NDA or NADA applicant states are not calculated in accordance with the June 7, 1995, determination. This document is intended to advise all NDA and NADA applicants who submitted URAA-extended patent term expiration dates that were not calculated in accordance with the PTO's determination to submit corrected patent term expiration dates to the agency.

DATES: NDA and NADA applicants that submitted inaccurate patent term expiration dates should submit patent term expiration dates calculated in accordance with the PTO's determination by August 21, 1995.

ADDRESSES: Two copies of amended patent information pertaining to human drug products regulated under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) by CDER should be submitted to the assigned reviewing division. The submission should bear the pertinent NDA number.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by CBER should be submitted to the Document Control Center, Center for Biologics Evaluation and Research (HFM–99), Food and Drug Administration, suite 200N, Rockville, MD 20852.

A third copy of the amended patent information pertaining to human drug products regulated under section 505 of the act by either the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) should be sent to the Division of Drug Information Services (HFD–85), Center for Drug Evaluation and Research, Food and Drug Administration, 1901 Chapman Ave., rm. 212, Rockville, MD 20852.

Amended patent information pertaining to animal drug products should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV–199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 8, 1995 (60 FR 30309), FDA announced the availability of the agency's response to a citizen petition from Glaxo, Inc., requesting that FDA explain how the URAA affects the patent information submission and patent certification requirements for applications to market drug products under the act. In that notice, FDA directed that amended patent information, reflecting extended patent term expiration dates under the URAA, be submitted to FDA between June 8 and July 8, 1995.

On June 7, 1995, the PTO published a notice in the **Federal Register** (60 FR 30069) entitled ''Determination of New Expiration Dates of Certain Patents'' (the PTO's determination) that established the method for calculating the patent term expiration date for any patent subject to both the terms of the URAA and the patent term extension provisions at 35 U.S.C. 156. FDA has received from several NDA or NADA applicants submissions of new patent term expiration dates which the applicant submitting the information states were not calculated in accordance with the PTO's determination. In order to comply with the requirements of sections 505(b) and 512(b) (21 U.S.C. 360b(b)) of the act and 21 CFR 314.53, NDA and NADA applicants must submit accurate patent information. For the expiration dates for patents that received patent term extension under the URAA to be accurate, those dates must be calculated in accordance with the PTO's determination.

FDA is advising all NDA and NADA applicants who submitted URAA-extended patent term expiration dates that were not calculated in accordance with the PTO's determination to submit corrected patent term expiration dates to the agency by August 21, 1995. If the applicant has already submitted patent expiration dates that are consistent with the PTO's determination, no additional submission is necessary. FDA will not verify the patent expiration dates submitted by NDA and NADA applicants. FDA will not publish any patent expiration date that the submitter states is not consistent with the PTO's determination.

The agency will publish the new patent term expiration dates submitted during the June 8 to July 8, 1995, period that are not expressly identified by the applicant submitting the information as having been calculated in a manner inconsistent with the PTO's determination. FDA anticipates that the procedures set out in § 314.53(f) will govern with respect to challenges by third parties that the submitted patent term expiration date was not calculated in accordance with the PTO's determination. For these challenges, the procedures set out in § 314.53(f) will be modified so that, if the applicant submitting the challenged patent term expiration date fails to notify FDA within 30 days of receiving notification from the agency of a challenge to the patent that the submitted date is consistent with the PTO's determination, FDA will not continue to publish the challenged date.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by CDER should be submitted to the assigned reviewing division. The submission should bear the pertinent NDA number.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by CBER should be submitted to the Document Control Center, Center for Biologics Evaluation and Research (HFM–99), Food and Drug Administration, suite 200N, Rockville, MD 20852.

To expedite the availability to the public of the updated patent information, a third copy of the amended patent information pertaining to human drug products regulated under section 505 of the act by either CDER or CBER should be sent to the Division of Drug Information Services (HFD–85), Center for Drug Evaluation and Research, Food and Drug Administration, 1901 Chapman Ave., rm. 212, Rockville, MD 20852.

Amended patent information pertaining to animal drug products

should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV–199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

Dated: July 18, 1995,

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–18079 Filed 7–19–95; 11:00 am]

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[Docket No. 95N–0207]

Owen/Galderma, et al.; Withdrawal of Approval of 1 New Drug Application, 23 Abbreviated New Drug Applications, and 5 Abbreviated Antibiotic Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 1 new drug application (NDA), 23 abbreviated new drug applications (ANDA's), and 5 abbreviated antibiotic applications (AADA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: August 21, 1995.

FOR FURTHER INFORMATION CONTACT: Lola Batson, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

Appication no.	Drug	Applicant
ANDA 18–795	Hydrocortisone Butyrate Cream, 0.1%	Owen/Galderma, 6201 South Freeway, P.O. Box 6600, Forth Worth, TX 76115.
NDA 50–610	Erythromycin U.S.P. for Extemporaneous Compounding of Topical Solutions.	Paddock Laboratories, Inc., P.O. Box 27286, Minneapolis, MN 55427.
AADA 62–656	Nystatin and Triamcinolone Acetonide Ointment, U.S.P.	Pharmafair, Inc., 8500 Hidden River Pkwy., Tampa, FL 33637.
AADA 62–657	Nystatin and Triamcinolone Acetonide Cream, U.S.P.	Do.
AADA 63–183	Cefamandole Naftate for Injection, U.S.P., bulk	Richmar International, Inc., 1706 Birch Rd., McLean, VA 22101.
AADA 63–184	Sterile Cefamandole Naftate, U.S.P	Do.
AADA 64–018	Amikacin Sulfate, U.S.P., nonsterile bulk	Do.
ANDA 70–077	Nitroglycerin Injection, U.S.P., 5 milligrams (mg)/milliliter (mL).	Fujisawa USA, Inc., 3 Parkway North, 3rd floor, Deerfield, IL 60015–2548.
ANDA 70–524	Dephenhydramine Hydrochloride Syrup, 12.5 mg/5 mL.	The Procter and Gamble Co., Sharon Woods Technical Center, 11450 Grooms Rd., Cincinnati, OH 45242–1434.
ANDA 70–648	Naloxone Hydrochloride Injection, U.S.P., 0.02 mg/mL.	Fujisawa USA, Inc.
ANDA 70–649	Naloxone Hydrochloride Injection, U.S.P., 0.04 mg/mL.	Do.
ANDA 72–191	Clofibrate Capsules, U.S.P., 500 mg	Geneva Pharmaceuticals, Inc., 2555 West Midway Blvd., P.O. Box 446, Broomfield, CO 80038–0446.
ANDA 83–951	Acetaminophen and Codeine Phosphate Tablets, U.S.P., 300 mg/30 mg and 300 mg/60 mg.	Burroghs Wellcome Co., 3030 Cornwallis Rd., P.O. Box 12700, Research Triangle Park, NC 27709–2700.
ANDA 83–963	Quinidine Sulfate Tablets, U.S.P., 200 mg	Vintage Pharmaceuticals, Inc., 3241 Woodpark Blvd., Charlotte, NC 28206.
ANDA 84–301	Hydralazine Hydrochloride Tablets, U.S.P., 25 mg	Lemmon Co., Inc., 650 Cathill Rd., Sellersville, PA 18960.
ANDA 84–969	Hydrocortisone Ointment, U.S.P., 0.5%	Clay-Park Labs., 1700 Bathgate Ave., Bronx, NY 10457.
ANDA 84–970	Hydrocortisone Cream, U.S.P., 0.5%	Do.
ANDA 85–026	Hydrocortisone Cream, U.S.P., 1%	Do.
ANDA 85–500	Phentermine Hydrochloride Tablets, U.S.P., 8 mg	Lemmon Co.
ANDA 85–662	Hydrocortisone Lotion, U.S.P., 0.5%	Clay-Park Labs.
ANDA 86–095	Chlorpheniramine Maleate Injection, U.S.P., 100 mg/mL.	Steris Laboratories, Inc., P.O. Box 23160, Phoenix, AZ 85063–3160.
ANDA 86–606	Aminophylline Injection, U.S.P., 25 mg/mL	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
ANDA 88–123	Isosorbide Dinitrate Tablets, U.S.P., 10 mg, sublingual.	Zeneca Pharmaceuticals, 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850–5437.
ANDA 88–407	Aminophylline Injection, U.S.P., 25 mg/mL, 100 mL vials.	Fujisawa USA, Inc.
ANDA 88–448	Dexamethasone Sodium Phosphate Injection, U.S.P., 4 mg/mL, vials.	Do.
ANDA 88–645	Dicyclomine Hydrochloride Capsules, U.S.P., 20 mg.	Lemmon Co.